

NOV - 2 2005

K050571

510(k) Summary.

This summary of Safety and Effectiveness is in accordance with the requirements of:

- Device Description:

Eurodent dental operative unit is an electrical device with air and water connections. It is composed from:

- A patient treatment chair moved electrically
- an hydric group with cuspidor and inside all suction, water, air and electrical circuits
- a dentist's instrument board
- an assistant board
- an electrical footswitch that controls same unit functions
- a dental light

- Intended Use:

Absolute America is a dental operative unit intended as an operative tool for therapeutic use on people by personnel highly skilled in dental practices, such as dentists, dental assistants and dental hygienists.

- Summary of Substantial Equivalence Comparison:

The proposed and predicated devices use similar components and are similar in design, technical characteristics and mode of operation. All the systems include a chair, dentist's instruments board, cuspidor, assistant board, dental light and footswitches for control of various function.

Dental operative unit ABSOLUTE AMERICA is substantially equivalent to Castellini S.p.A. dental operative unit model "Logos Junior" and to American Dental Technologies dental operative unit model "Gulliver and Classe A Dental Operative Unit".



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV - 2 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Eurodent S.P.A.
C/O Mr. Avi Politi
Managing Director
Eurodent USA
79 Hudson Street
Hoboken, New Jersey 07030

Re: K050571
Trade/Device Name: ABSOLUTE AMERICA
Regulation Number: 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: I
Product Code: EIA
Dated: September 29, 2005
Received: October 11, 2005

Dear Mr. Politi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin", with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indication for use.

Applicant: EURODENT S.p.A.

510(k) Number (if known): K050571

Device Name: ABSOLUTE AMERICA

Indication For Use: Absolute America is a dental operative unit intended as an operative tool for therapeutic use on people by personnel highly skilled in dental practices, such as dentists, dental assistants and dental hygienists.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED).

Concurrence of CDRH, Office of Device Evaluation (ODE).

Rei Muly for MSR
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K050571